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## INTERBODY CAGE TYPE IMPLANT, AND INSTRUMENTATION AND METHOD FOR POSITIONING SAME

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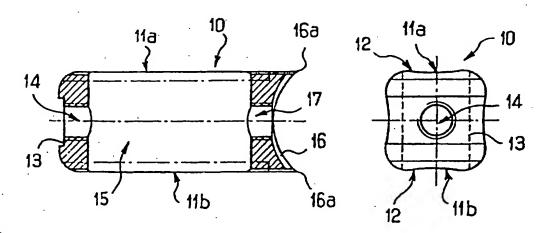
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#### (57) Abstract

An interbody cavity type implant (10) for insertion into a hole provided in a region separating two adjacent vertebral bodies. The implant includes an elongate rigid body and has a generally non-circular cross-section. Said implant is designed to be inserted into a generally cylindrical hole and its front end comprises a plurality of sharp ridges (16a) forming gouges which, by impaction, can shape the hole according to the cross-section of the implant. Instrumentation for positioning the implant is also disclosed.

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The present invention generally concerns the interbody implants used in traumatology of the spine.

More particularly, it concerns a new rigid interbody cage as well as a tool and a procedure for its positioning.

Usually, such an implant is in the shape of a cylindrical body made of a metal or biocompatible metal alloy. A cylindrical hole is formed with the aid of a rotating tool in the intervertebral space and the implant is positioned in the hole, with the aid of a relatively basic accessory.

This implant and its procedure for positioning however, suffer from a certain number of drawbacks.

Firstly, because of the rotating form of the implant, the stability of the position of the latter is not guaranteed.

In addition, its positioning with the aid of a nonspecific accessory is extremely delicate and tedious especially insofar as it is necessary to keep the vertebral bodies appropriately distracted to prepare the hole designed for the implant and for positioning the implant.

Practically, it is frequent that at the end of a procedure for positioning an interbody cage, the latter works loose, is displaced and no longer fulfills its function.

Cylindrical implants with the above-mentioned drawbacks are already known from WO-A-89 09035. This same document also describes an implant with a square cross section, a cross section unadaptable to cylindrical piercing, and the work for preparation of the hole therefore becomes much more tedious.

The present invention aims to overcome the drawbacks of the state of the art.

Thus, the present invention first proposes an interbody cage type implant, of the type designed to be received in a hole formed in the region separating two adjacent vertebral bodies, and comprising an elongated rigid body whose cross section is generally noncircular in shape, characterized in that it is designed to be received in a generally circular hole and in that it includes at its anterior end a plurality of sharp ridges forming gouges, making it possible to conform to the hole according to the cross section of the implant by impaction.

Preferred, but not limiting, aspects of this implant are the following:

- -The transverse cross section of the implant is generally square in shape with rounded corners while its anterior surface is generally concave, thus forming four sharp ridges forming gouges and ensuring the capturing of bone debris pulled out by the ridges during impaction.
- -The upper and lower surfaces of the implant each include serrations designed for the self-stabilization of the implant in its compartment.
  - -The upper, lower and lateral surfaces of the implant have a slightly concave profile.

- -In the region of its posterior surface the implant comprises means for attachment of an instrument designed for its positioning in its compartment by a posterior route.
- -The means of attachment comprises a threaded hole formed centrally in said posterior surface.
- -In addition, in the region of its posterior surface the implant comprises a means for the indexing in the axial direction and in rotation of the implant in comparison to said instrument.
- -The indexing means comprises a groove formed in said posterior surface and at the bottom of which is formed the threaded hole.
- -In the region of its anterior surface the implant comprises means for attachment of an instrument designed for its positioning in its compartment by an anterior route.
- -The means of attachment comprises a threaded hole formed centrally in said anterior surface.
- -The implant comprises a traversing slot extending from its upper surface to its lower surface.
  - -The upper and lower surfaces of the implant are oriented parallel to each other.
- -The upper and lower surfaces of the implant are slightly inclined in comparison with each other in order to treat lordosis.

According to a second aspect of the invention, a combination of an implant of the interbody cage type and an instrumentation for its positioning by the posterior route is proposed in a region situated between two vertebral bodies characterized in that the implant comprises an elongated rigid body presenting a cross section generally noncircular in shape and including at its anterior end a plurality of sharp ridges forming gouges, the implant also including at the anterior end a threaded means and an indexing means with complementary shapes and characterized in that the instrumentation comprises:

- -a first elongated tool designed for distraction of adjacent vertebral bodies from each other between which the implant must be placed;
- -a tubular guiding instrument designed to be positioned around the first tool and including means designed to be anchored in the vertebral bodies so as to keep them spread apart after distraction, and so as to retain said guiding instrument in a reference position,
- -a second tool forming a borer designed to be received in the guiding instrument and by rotating form a cylindrical hole generated by rotation between the vertebral bodies, and
- -a third tool for positioning the implant by impaction, including at one end a threaded means designed to cooperate with the threaded means of the implant and an indexing means designed to cooperate with the indexing means of the implant, and designed to be engaged with the implant in the guiding instrument.

Preferentially, the first tool comprises a body including at one end a distraction part with an elongated cross section, and on the other end an immovable handle.

Particularly advantageously, the tubular guiding instrument has an internal cross section so that it can be engaged practically without play, but with the possibility of rotation around the first tool.

According to one preferred embodiment, the tubular guiding instrument includes at one end two pins designed to be engaged in the two vertebral bodies by impaction.

Also, preferably, the instrumentation comprises in addition a recessed impaction tool cooperating with the end of the guiding instrument opposite the pins while going around the equivalent end of the first tool which projects from said guiding instrument and through which impacts can be applied to the guiding instrument.

According to an advantageous characteristic, the second tool comprises a body capable of being engaged practically without play, but with the possibility of rotation, in the tubular guiding instrument, at a first end of the body a borer provided with an overall cross section equal to or less than that of the body and at a second end of the body a handle provided for driving by rotation.

According to another advantageous characteristic, the third tool comprises a hollow body capable of being engaged practically without play but with the possibility of rotation, in the tubular guiding instrument, a rod mounted so that it slides and rotates in the hollow body and including at the first end the threaded means in the form of a threaded rod and at the second end a knurled knob for driving with rotation of the rod, and said hollow body has at its end equivalent with the first end of the rod the indexing means cooperating with the indexing means of the implant.

Other aspects, goals and advantages of the present invention will become clearer in following detailed description of a preferred embodiment of the latter, given by way of example and made in reference to the attached figures, in which:

Figure 1 is a top view of an interbody cage according to the invention,

Figure 2 is a sectional view along line II-II of Figure 1,

Figure 3 is a view along arrow III in Figure 1,

Figure 4 is a vertical view in magnified scale of a detail of the cage of Figures 1 to 4,

Figure 5a and 5b are two vertical views of a side of a part of a set of tools used in the first positioning step of the cage of Figures 1 to 4,

Figure 6 is a partial axial profile of a part of a set of tools used in the second positioning step,

Figure 7 is a partial axial profile of a part of a set of tools used in the third positioning step,

Figure 8 is a partial axial profile of a part of a set of tools used in the fourth positioning step,

Figure 9a is a side elevation of part of the set of tools used in the fifth positioning step, Figure 9b is a horizontal axial profile of part of the set of tools of Figure 9a,

Figure 10 is a partial axial profile of part of the set of tools used in the sixth positioning step,

Figure 11 is a partial axial profile of part of the set of tools used in the seventh positioning step, and

Figure 12 is a diagrammatic vertical view of the side of an interbody cage according to an execution variant of the invention.

Preliminarily, it will be noted that from one figure to the other, identical or similar units or parts are designated insofar as possible by the same reference numbers.

First, in reference to Figures 1 to 4, an interbody cage type implant 10 which has the general shape of an elongated body with a generally square cross section with rounded corners. The upper, lower and lateral surfaces all have a central concavity, designed to favor the angular stability of the implant.

The upper and lower surfaces 11a, 11b of the cage each have serrations 12 designed for the stabilization of the position of the implant between two vertebral bodies, this serration ensuring anchoring in the adjacent bone walls and consequently, good locking of the implant against movements in the axial direction.

This serration is represented in detail in Figure 4, where it concerns the upper surface, and has a series of transverse teeth 12a triangular and symmetrical in profile in which the angle at the peak is designated by  $\alpha$ .

The end of the implant situated on the right in Figures 1 and 3 (end called anterior) has a concave surface 16, for example, in the shape of a portion of a sphere.

This concavity makes it possible to define, at the rounded corners of the implant at this surface, four sharp ridges which, as will be seen later, act as gouges during positioning of the implant. At the center of the concave surface 16 is an axial threaded attachment hole 17, for purposes to be explained later.

The opposite or posterior surface of the implant, as Figures 1 to 3 show, is generally straight. It has along its entire width a transverse groove 13 that is not very deep with straight edges, at the center of which is made an axial threaded attachment hole 14.

Finally, implant 10 is crossed from one side to the other, between its upper and lower surfaces 11a, 11b by an oblong slot 15 with a constant, straight cross section, for purposes to be explained later.

The preferred dimensions are indicated below, but are in no way limiting, for the interbody cage described above:

Overall length:

25 mm

Width:

10.5 mm

Height:

10.5 mm

Radius of curvature of rounded corners: 2.2 mm
Radius of curvature of central concavity: 20 mm
Radius of curvature of concave surface 16: 8 mm

Angle  $\alpha$  at the peak of the anchoring teeth: 90°

Width of the teeth:

2 mm

Height of the teeth: 1 mm Height of groove 13: 5 mm Depth of groove 13: 0.5 mm

The instrumentation and procedure will be described in detail for the positioning of the implant described above in the space situated between two vertebral bodies of the human spine, as well as the various functions given by the geometry of the implant.

First, conventionally, the preparation of the first route will be carried out. Then, a partial distraction of the interbody space, not illustrated, is carried out on the side of the disk opposite that being prepared to treat.

In reference to Figures 5a and 5b, a distraction tool is illustrated that is designated overall by the reference number 100, which comprises a revolving cylindrical principal body 102. At one end of this body is extended axially an intermediate part 104 including at its free end a tool in the form of a spatula 106 with an oblong profile, for example elliptical.

At the opposite end of the body is extended axially a rod 108 on which an operating handle 109 can be mounted immovably, for example snapped, reference number 107 designating a releasing means of said handle.

It is observed from Figure 6 that the snapping is done by means of a groove 108a formed in the rod 108.

Tool 100 as represented in Figures 5a and 5b makes it possible, as the first step of the procedure for positioning the implant, to carry out distraction of the two vertebral bodies CV1 and CV2 between which the implant must be positioned. More precisely, by inserting spatula 106 with force into the intervertebral space, and by carrying out rotation of the tool by a quarter

of a turn according to arrow F5 in Figure 5a, the two vertebral bodies are made to distract to an appropriate distance (Figure 5b). This distance, fixed by the width of the spatula 106 is preferably slightly less than the height of the interbody cage to be positioned.

Now, in reference to Figure 6, tool 100 is illustrated kept in the position of Figure 5b, handle 109 having been removed.

Then, an instrument designated overall by 110 is engaged on cylindrical body 102 of tool 100. This instrument comprises a hollow cylindrical shaft 112, the internal diameter of which is slightly less [sic] than the external diameter of body 102 of tool 100. This shaft includes at its end turned towards the spine two pointed pins 113 arranged diametrically, mounted on the shaft through a spindle ring and at its opposite end a solid handle 114 of the shaft 112. Moreover, it is observed in Figure 6 that the two pins 113 of the instrument 110 are arranged so as to be situated, respectively, on the right of the two vertebral bodies CV1, CV2.

In the rest of the positioning procedure, instrument 110 has the goal of ensuring operating guidance by defining a reference axis for intervention and as will be seen below of keeping the vertebral bodies appropriately distracted from each other. It will be noted that after having engaged the guiding instrument 110 on tool 100, a certain setting of alignment can be carried out to align it by comparison with the longitudinal axis of the patient.

In reference to Figure 7, it represents instrument 110, tool 100 contained within the latter and another tool indicated overall as 120 designed to make it possible to apply axial impacts to instrument 110. This tool 120 has the shape of a recessed tube surrounded by a cylindrical skirt 122, with play, the end part of the tool 100, which protrudes through the open end of instrument 110, and the top part 124 of which is a certain distance from the end of tool 100. The free edge of the skirt 122 opposite top 124 is supported on the hollow cylindrical body 112 of instrument 110 at the level of the handle 114.

Impacts are then applied along arrow F7 on the top 124 of the tool 120, these impacts being transmitted to the guiding instrument 110 to drive the two pins 113 into the respective vertebral bodies CV1, CV2 like a nailing. It will be observed that this operation is carried out while the first tool 100 remains in position and ensures the distraction of the two vertebral bodies.

Figure 7 shows the position of the instrument 110 at the end of this operation.

Once this operation is carried out, the bell 120 is withdrawn, the handle 109 is remounted on the tool 100 and traction can be exerted on the tool 100 with the aid of said handle to extract the blade 106 from the intervertebral space, and to completely remove tool 100 from the guiding instrument.

Instrument 110 then forms a guide-tool for the all the rest of the operations as will be seen below.

In reference to Figure 8, a second tool 130 is inserted in the guide instrument 110 instead of the first tool 100. This tool comprises a cylindrical body 132 the diameter of which is very slightly less than the interior diameter of shaft 112, with a rod 134 extending axially to one end of the body 132 and a borer 136 provided at the free end of the rod 134.

At its opposite end, tool 130 includes an attached or immovable handle 138. By making tool 130 turn with the aid of the handle 138 and by simultaneously exerting pressure on the tool, a cylindrical attachment hole generated by rotation is formed in the space situated between the vertebral bodies. The movements of the tool 130 are symbolized by arrow F8.

Preferably, the diameter of the borer 136 is equal to the overall width and the height of the implant 10 described with reference to Figures 1 to 4. These dimensions are chosen so as to be slightly greater than the height of the interbody space, fixed by the width of the spatula 106 of tool 100. Thus, the borer removes disc material and also a small amount of bone material from the vertebral end plates.

Once a hole with appropriate depth has been formed (this depth can be controlled for example by a stop cooperating between tool 130 and guide 110, or even by a gradation formed on the body 132 of tool 130), this latter is then extracted from guide 110.

The following operation consists of mounting implant 10 on a third tool represented in Figures 9a and 9b. The slot 15 of the implant is previously filled with bone grafts that will act after positioning to establish a bone connection between the two vertebral bodies.

This tool 140 is presented in two parts, namely an external part including a cylindrical shaft 141 and an internal part including a cylindrical body 143 that can slide and turn freely, but practically without play in the shaft 141.

Shaft 141 includes at its anterior end (on the left in Figures 9a and 9b) a noncylindrical extension, and more particularly an extension 142 limited by two straight edges, the distance of which is slightly less than the distance between the straight edges of the groove 13 of the implant. Near its posterior end the external part of tool 140 includes two wings 148 for purposes to be explained later.

The internal part of tool 140 includes its anterior end, threaded rod 144 extending axially from body 143. This threaded rod freely crosses the end of the external part of tool 140 in which the extension 142 is used. A shoulder 146 formed in the exterior of shaft 141 limits the axial displacement of the internal part of the tool.

At its opposite end, body 143 is attached to a knurled knob 145 designed to drive by rotation.

The mounting of the implant 10 on tool 140 is carried out by engaging by screwing the threaded rod 144 in the threaded attachment hole 14 of the implant, while the end 142 of the external part is kept in alignment with the groove 13 of the implant. The rotation of the threaded rod 144 is carried out with the aid of the knurled knob 145.

After tightening, the implant 10 is attached to tool 140 as much for rotation as for translation as a result of the cooperation of the screwing and the complementarity of the shapes between the conformed end 142 of the tool and groove 13.

The unit thus obtained, represented in Figures 9a and 9b is engaged in the guiding instrument 110.

In reference to Figure 10, it is observed that shaft 112 of instrument 110 includes at its posterior end (on the right) two notches 112a, which are suited to receive the wings 148 of tool 140. In this way tool 140 can only be engaged in the guiding instrument 110 in a predetermined angular position, which corresponds to a position of implant 10 in which the upper and lower walls 11a, 11b are opposite the two vertebral bodies.

Then axial impacts are applied on tool 140 at the knurled knob 145. These impacts make it possible for the implant to progressively penetrate into the cylindrical attachment hole formed by the borer (see Figure 8), the four sharp ridges 16a of the implant as described above acting as gouges to increase the threaded hole in their region by attacking the bone material of the vertebral bodies. Here, as this work progresses by the set of tools, it will be observed that the concavity of the anterior surface 16 of the implant 10 makes it possible to drive out the pieces of bone that are freed before the implant while accumulating them at the bottom of the hole. Therefore, according to an important characteristic of the invention, it is the implant itself which intervenes as the last tool for its positioning. Thus, it is the implant which itself conforms, from a cylindrical hole previously generated by rotation, to a compartment having exactly the same cross section as the implant, which guarantees its stability.

Once the implant positioned with the desired depth (determined practically by arrival with wings 148 stopped at the bottom of grooves 112a), the knurled knob145 of tool 140 is turned to unscrew the threaded rod 144 from the threaded attachment hole 14 and free tool 140. This movement is symbolized by arrows F11a. Tool 140 is then removed from the guiding instrument 110 either in a single step or in two steps (internal part then external part). Refer to Figure 11 that illustrates the partial withdrawal of the internal part of tool 140.

Finally, by exerting traction at the level of the handle 114 (arrows F11b), the guiding instrument 110 distracts vertebral bodies CV1, CV2. The two vertebral bodies then tend to approach each other naturally and to hold the implant 10 tightly. The serrated surfaces 12 of the

latter are then anchored in the bone material of the vertebral bodies to still improve the stability of the implant.

Here it will be observed that the vertical slot 15 formed in the implant and filled with grafts before positioning makes it possible to ensure a connection between the overlying and underlying vertebral bodies via bone over time through the grafts. It will be noted in this regard that the self-tooling action of the implant during its positioning makes it possible to ensure cleaning of the surfaces opposite the two vertebral bodies, which will facilitate the meshing of the graft.

Thus, an instrumentation and procedure for positioning of an interbody cage has been described by the posterior route that presents a certain number of advantages. The work is carried out rapidly and with great precision, and the stability of the implant once positioned is excellent.

As described in reference to Figures 1 to 3, implant 10 also has a threaded attachment hole 17 in its anterior surface. This attachment hole makes it possible for it to be attached at the front with the tool 140 to make positioning possible by the anterior route when the latter is made necessary. In this case, the compartment for the implant is at least partially preformed manually.

In reference to Figure 12, an embodiment variant of the implant is represented that is adapted to lordosis; that is, to a nonparallel situation between the opposite surfaces of the two vertebral bodies (lumbar vertebrae). In this case, the upper 11a and lower 11b surfaces of the implant 10 have a certain obliqueness in comparison to each other, adapted to lordosis. In this case, the hole made with the aid of a borer has a diameter approximately equal to the smallest height of the implant.

Of course, the present invention is in no way limited to the embodiments described and represented, but the specialist trained in the art will know how to bring to it any variant or modification that conforms to its intent.

#### Claims

- 1. Interbody cage type implant (10), of the type designed to be received in a hole formed in the region distracting two adjacent vertebral bodies (CV1, CV2), and comprising an elongated rigid body whose cross section is generally noncircular in shape, characterized in that it is designed to be received in a generally circular hole and in that it includes at its anterior end a plurality of sharp ridges (16a) forming gouges making it possible to conform the holes according to the cross section of the implant by impaction.
- 2. Implant according to Claim 1 characterized in that its transverse cross section is generally square in shape with rounded corners and in that its anterior surface (16) is generally

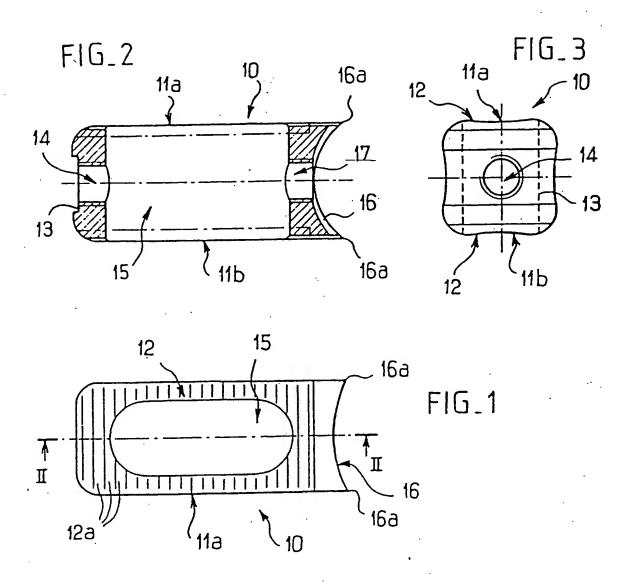
concave, thus forming four sharp ridges forming gouges (16a) and ensuring the capturing of bone debris pulled out by the ridges during impaction.

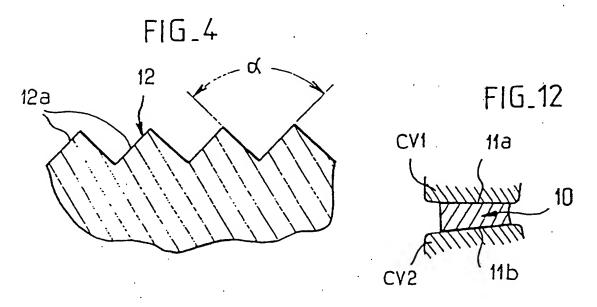
- 3. Implant according to Claim 2 characterized in that its upper and lower surfaces (11a, 11b) each include serrations (12) designed for the self-stabilization of the implant in its compartment.
- 4. Implant according to one of Claims 2 and 3 characterized in that the upper, lower and lateral surfaces of the implant have a slightly concave profile.
- 5. Implant according to one of Claims 1 to 4 characterized in that in the region of its posterior surface it comprises means (14) for attachment of an instrument designed for its positioning in its compartment by a posterior route.
- 6. Implant according to Claim 5 characterized in that the means of attachment comprise a threaded hole (14) formed centrally in said posterior surface.
- 7. Implant according to Claim 5 or 6 characterized in that in addition, in the region of its posterior surface it comprises a means (13) for indexing in the axial direction and in rotation of the implant by comparison with said instrument.
- 8. Implant according to both Claims 6 and 7 characterized in that the indexing means comprises a groove (13) formed in said posterior surface and at the bottom of which is formed the threaded hole.
- 9. Implant according to one of Claims 1 to 8 characterized in that in the region of its anterior surface it comprises a means (17) for attachment of an instrument designed for its positioning in its compartment by an anterior route.
- 10. Implant according to Claim 5 characterized in that the means of attachment comprises a threaded hole (17) formed centrally in said anterior surface.
- 11. Implant according to one of Claims 1 to 10 characterized in that it comprises a traversing slot (15) extending from the upper to lower surface.
- 12. Implant according to one of Claims 1 to 11 characterized in that its upper and lower surfaces (11a, 11b) are oriented parallel to each other.
- 13. Implant according to one of Claims 1 to 11 characterized in that its upper and lower surfaces (11a, 11b) are slightly inclined in comparison to each other.
- 14. Combination of an implant (10) of the interbody cage type and an instrumentation for its positioning by the posterior route is proposed in a region situated between two vertebral bodies (CV1, CV2) characterized in that the implant comprises an elongated rigid body presenting a cross section generally noncircular in shape and including at its anterior end a plurality of sharp ridges (16a) forming gouges, the implant also including at the anterior end a

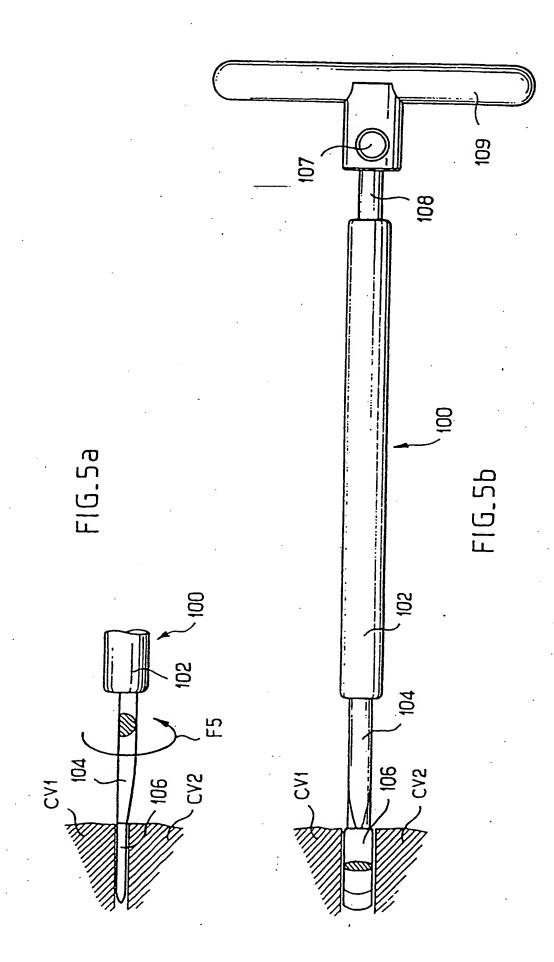
threaded means (14) and an indexing means (13) with complementary shapes and characterized in that the instrumentation comprises:

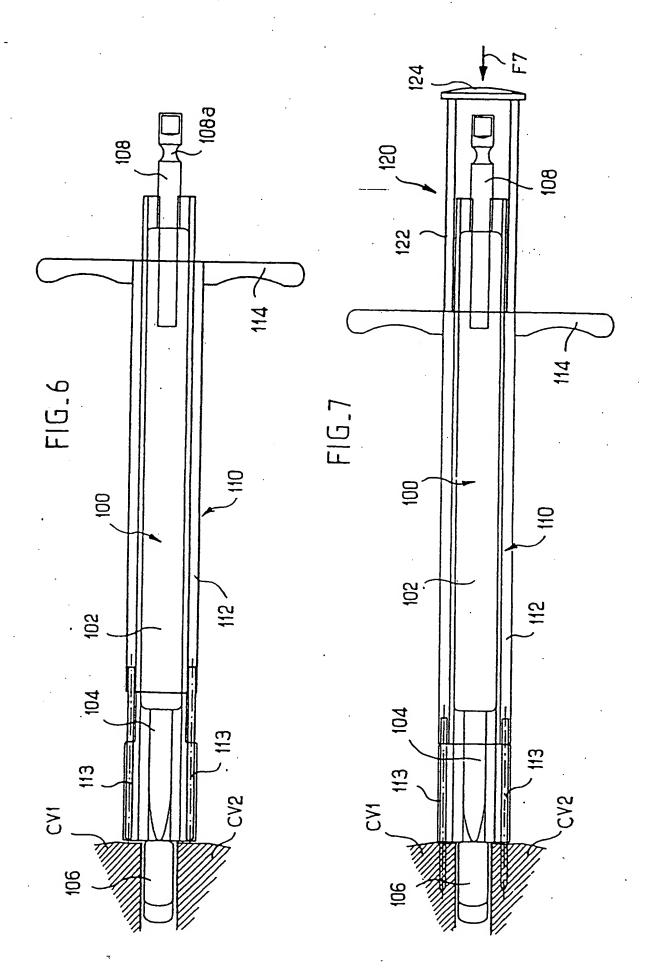
- -a first elongated tool (100) designed for distraction of adjacent vertebral bodies from each other between which the implant must be placed;
- -a tubular guiding instrument (110) designed to be positioned around the first tool and including means (113) designed to be anchored in the vertebral bodies so as to keep them spread apart after distraction, and so as to retain said guiding instrument in a reference position,
- -a second tool (130) forming a borer designed to be received in the guiding instrument and by rotating form a cylindrical hole generated by rotation between the vertebral bodies, and
- -a third tool (140) for positioning the implant by impaction, including at one end a threaded means (144) designed to cooperate with the threaded means of the implant and an indexing means (142) designed to cooperate with the indexing means of the implant, and designed to be engaged with the implant (10) in the guiding instrument.
- 15. Combination according to Claim 14 characterized in that the first tool (100) comprises a body (102) including at one end a distraction part (106) with an elongated cross section, and on the other end an immovable handle (109).
- 16. Combination according to Claim 15 characterized in that the tubular guiding instrument (110) has an internal cross section so that it can be engaged practically without play, but with the possibility of rotation around the first tool (100).
- 17. Combination according to Claim 16 characterized in that the tubular guiding instrument (110) includes at one end two pins (113) designed to be engaged in the two vertebral bodies (CV1, CV2) by impaction.
- 18. Combination according to Claim 16 or 17 characterized in that the instrumentation comprises in addition an impaction tool (120) cooperating with the end of the guiding instrument (110) opposite the pins by going around the equivalent end of the first tool (100) which projects from said guiding instrument and through which impacts can be applied to the guiding instrument.
- 19. Combination according to one of Claims 16 to 18 characterized in that the second tool (130) comprises a body (132) capable of being engaged practically without play, but with the possibility of rotation, in the tubular guiding instrument, at a first end of the body a borer (136) being provided with an overall cross section equal to or less than that of the body and at a second end of the body a handle (138) being provided for driving with rotation.
- 20. Combination according to one of Claims 16 to 19 characterized in that the third tool (140) comprises a hollow body (141) capable of being engaged practically without play but with the possibility of rotation, in the tubular guiding instrument, a rod (143) mounted so that it slides

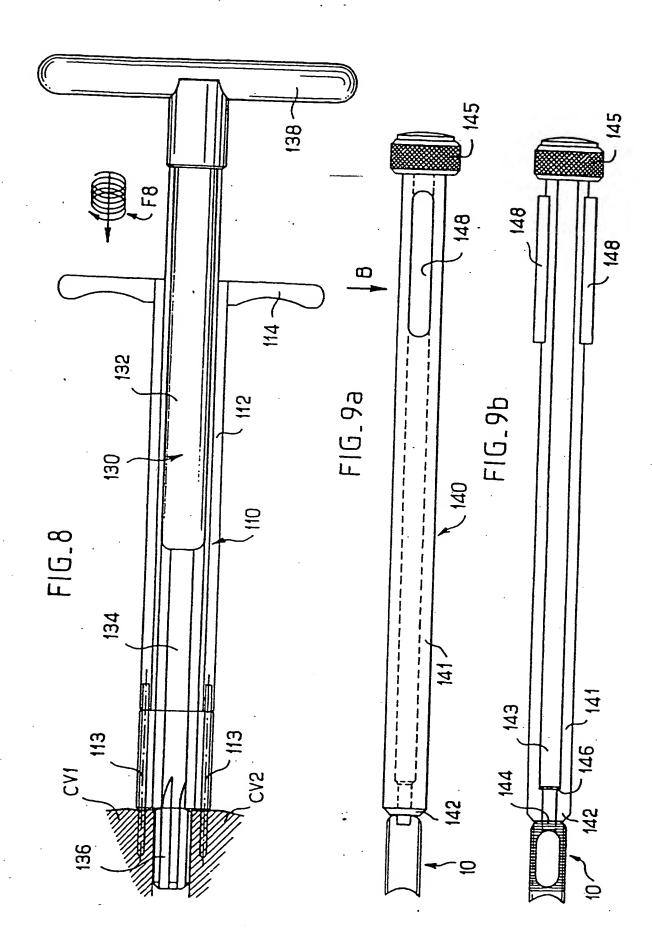
and rotates in the hollow body and including at the first end the threaded means (144) in the form of a threaded rod and at the second end a knurled knob (145) for driving by rotation of the rod, and said hollow body (141) has at its end equivalent with the first end of the rod the indexing means (142) cooperating with the indexing means (13) of the implant (10).

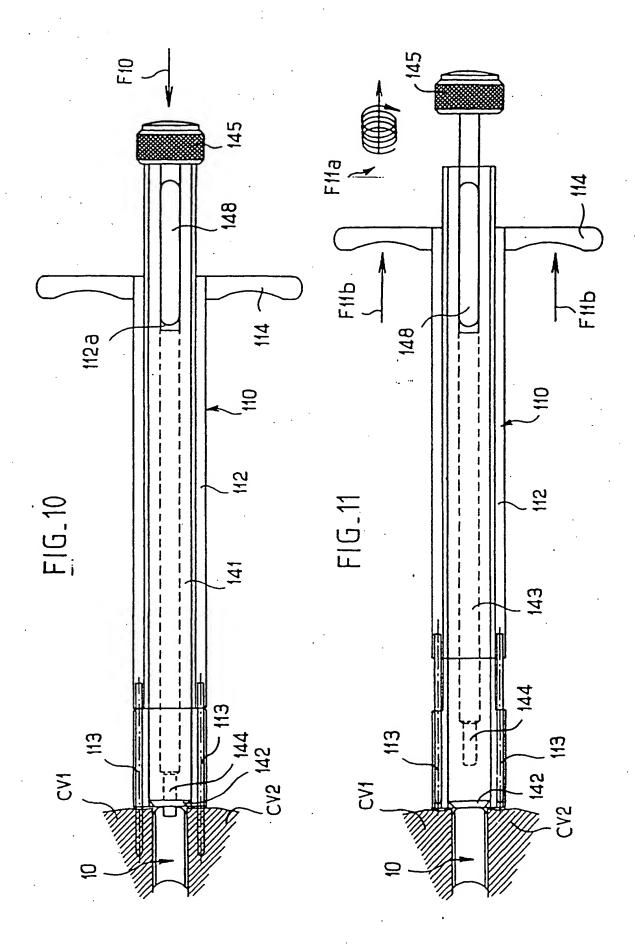












Interna — il Application No PCT/FR 96/00108

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A. CLAS	SEFICATION OF SUBJECT MATTER A61F2/44 A61B17/70 A61B1	7/58	
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C. DOCU	MENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of th	e relevant passages	Relevant to claim No.
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	Tel. (+31-70) 340-2040, Tx. 31 651 epo al, Fax: (+31-70) 340-3016	Douskas, K	

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